Remarks

Applicant has amended the claims to add new claim 16 which is specifically drawn to the adaptor element of the connection system. Support for this claim is found in the specification as a whole and, for example, in original claim 1 and paragraphs [0013], [0014], [0034], [0038], [0039], [0042] and [0043]. No new matter is introduced by this amendment.

Claims 1-16 are now pending with claims 1-15 rejected under Section 103 (a) as being unpatentable over Groshong in view of Kanno as further modified by O'Neil.

Applicant respectfully disagrees with the rejections based on Section 103 and argues in more detail below that the cited references neither teach nor suggest Applicant's invention, particularly the alleged disclosure of an "adaptor" in the Groshong reference. The first sentence of Applicant's Summary of Invention recites that "[t]he present invention is fundamentally a connection system for connecting a hemostasis valve to a sheath." (Page 4, paragraph [0011] of Applicant's specification as filed). Applicant respectfully asserts that the element alleged to be an "adaptor" in Groshong is not even suggestive of an "adaptor" and one skilled in the art and would consider that element to be wholly inappropriate for connecting a hemostasis valve to a sheath.

Rejections under 35 U.S.C. § 103(a)

"Claims 1-15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Groshong (US 4,772,266) in view of Kanno (US 4,629, 455) as further modified by O'Neill (US 4,436,519)." (Office action at 2)

The Examiner has alleged that regarding claims 1, 2, 7, 9, 10, 11 and 15 that "Groshong discloses a splittable sheath (14) comprising a threaded nipple (110, 122) and an adaptor (12) comprising a threaded shaft (24, 38), a cannula (22) interfacing with the lumen of the sheath (20), and a sliding connector (56) comprising internal threading (64) for engagement with the engagement means of the sheath and an annular lip (52) extending radially inward." Applicant respectfully disagrees.

In order to make out a *prima facie* case of obviousness, "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references *for combination in the manner claimed*." In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998).

Figures 3, 4 and 5 of Groshong illustrate all of the elements alleged by the Examiner. Both the cross-sectional view (Fig. 3) and the isometric view (Fig. 4) show the alleged "splittable sheath" (14) and the alleged "adaptor" (12). When searching for the alleged "lumen of the sheath (20)" however, this element can only be found in Figure 5. Noticeably absent from Figure 5 is element 12 – the alleged "adaptor."

A close reading of Groshong reveals the reason for the discrepancy. The alleged "lumen of the sheath (20)" is actually identified as a "catheter tube" (Col. 5, lines 59-60) in Groshong. The alleged "adaptor" is identified as a "dilator." (Col. 2, lines 61-62). Applicant respectfully asserts that one skilled in the art would have no reason to understand that the dilator of Groshong teaches or suggests an "adaptor" capable of being used in a connection system for a hemostasis valve and sheath.

> The objective of the dilator/sheath assembly 10, is to use the same in the assembled condition shown in FIG. 1 by advancing the assembly 10 telescopically over a guide wire indwelling in a vein, an artery or other body cavity of a medical patient and to force first the tapered distal end 16 of the ***dilator 12*** through the puncture site to enlarge the same and thereafter to likewise force the tapered distal end 18 of the sheath assembly 14 through the puncture site to further enlarge the same, ***all preparatory to insertion*** of a flexible catheter tube 20 (FIG. 5) . . . . (Groshong at col. 2 lines 64-col. 3, line 5).

The dilator in Groshong functions to gently urge a sheath through a relatively small venipuncture by gradually dilating the venipuncture around its tapered distal edge. The dilator is ***withdrawn*** as soon as the sheath is seated: ". . . rotation of essentially 90 degrees will separate the female coupling member 50 from the male coupling member 110 *to accommodate thereafter telescopic withdrawal of the dilator 12 from the sheath 14. See FIG. 4."* (Col. 5, lines 50-54).

Indeed, although the Examiner has alleged that the alleged "adaptor" partially comprises "a cannula (22) interfacing with the lumen of the sheath (20)" (Office action at page 2), at the time element (20) appears (in Figure 5) the alleged "adaptor" has already been withdrawn. Contrast Figures 4 and 5 of Groshong with Applicant's Figure 3. Figure 4 of Groshong shows the alleged "adaptor" being withdrawn from the alleged "sheath" and Figure 5 shows the alleged "adaptor" after it has been completely withdrawn and replaced by a catheter. Figure 3 illustrates the relationship of Applicant's adaptor fitting (56) to the sheath (76) and the connector lumen (86) to which the hemostasis valve is attached.

Applicant respectfully asserts that the Examiner's characterization of the dilator of Groshong as an "adaptor" is misplaced. At a minimum, the Examiner has presented no rationale which would explain why one of ordinary skill would understand the problem of creating a connection system for a hemostatic valve and sheath to be related in any manner to the use of a dilator. Additionally, there is no suggestion that the elements in Groshong have been combined "in the manner claimed" since the Examiner has presented no rationale for how the hemostatic valve remains connected to the sheath after the alleged "adaptor" is removed. Accordingly, the rejections based on Groshong should be withdrawn.

Regarding claims 3, 6 and 8, the Examiner has also alleged that Groshong discloses "an elastomeric O-ring (44)" and sealing means which "creates a fluid seal." (Page 2 of Office action). Applicant respectfully asserts that there is no teaching or suggestion in Groshong that fluid seals are present or even desired. There is no teaching or suggestion anywhere in Groshong of "elastomeric O-rings" and Applicant respectfully asserts that the "annular forward ring (44)" found in Groshon is not suggestive of an "O-ring" as that term is understood by those skilled in the art. The term "seal" appears nowhere in Groshong and the passage cited by the Examiner to support the assertion that a fluid seal is present merely recites that the coupling members "create a releasable but locked relationship between the dilator 12 and sheath 14." (Col. 4 lines16-17). Groshong makes clear throughout its text and in the claims that the

"present invention insures a stable ***axial relationship*** between the superimposed sheath and dilator so that use is very facile for the medical attendant and insures a predetermined two-step gentle enlargement of the puncture site . . . ." (emphasis added, Col. 2, lines 1-5). No seal is mentioned and the focus on a puncture site has nothing to do with Applicant's claimed invention. Indeed, the sentence just preceding the section cited by the Examiner recites that "[t]he diameter of surface 62 is substantially greater than the outside diameter of cannula 22." (Col. 4, lines 13-14). An O-ring is nowhere mentioned. The Examiner has presented no rationale to explain why the cited section teaches or even suggests the presence of or desirability of a fluid seal or O-ring. Therefore, these rejections should be withdrawn.

The Examiner has additionally asserted that "Kanno teaches it is known to use two wedges (19) spaced 180 degrees apart on a cannula in Figure 3." (Office action at page 3). Applicant respectfully disagrees. The alleged "wedges" are actually "an engaging portion 19 formed on the outer periphery of the neck portion 18 . . . ." Additionally, "[t]he rotary ring 17 is adapted to be attached fast to the neck portion of the male connector member 12 by causing a hole 20 . . . and slid over the engaging portion 19 by virtue of mutual elastic deformation of the engaging portion 19 and the hole." (Col. 4 lines 49-59).

Figure 3 of Kanno cited by the Examiner is a cross-sectional view. There is nothing in the specification that suggests that element 19 is a "wedge" at all. In fact, by reciting that the engaging portion 19 is "formed on the outer periphery" (Kanno at col. 4, lines 49-50), one skilled in the art would likely conclude that 19 extends around the entire periphery. If Kanno had included an isometric view, the alleged "wedge" would appear as a flared "ring" around the periphery of the neck portion 18. Such a ring would also create a stable connection around the entire circumference of the rotary ring 17. Contrast Figure 3 of Kanno with the wedges 70 found in Applicant's isometric view (Figure 3). Since Figure 3 of Kanno does not teach or suggest "wedges," the rejections should be withdrawn.

Finally, the Examiner has alleged that "O'Neill teaches in Figure 2 that it is known to use a hemostasis valve with internal threading connected to an adaptor which is further connected to a sheath." (Office action at Page 3). As argued above, Applicant's have demonstrated that the alleged "adaptor" of Groshong is designed to be withdrawn immediately after placement of the sheath. Since the Examiner has provided no rationale to explain how the hemostasis valve of O'Neill would remain connected to the sheath after the alleged "adaptor" has been withdrawn, Applicant's respectfully assert that the elements of Groshong and O'Neill have not been combined as claimed. The rejection should be withdrawn.

Applicant submits that the application is in condition for allowance. Timely notification of allowability is requested.

Applicant has added an additional independent claim and attached the requisite fee. No additional fees, requests for extension of time, other petitions, additional claim fees, or any other fees are believed to be necessary to enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, Applicant hereby requests any extensions or petitions necessary and the Commissioner is hereby authorized to charge our Deposit Account No. 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, or if the payment or fee payment information has been misplaced or is somehow insufficient to provide payment, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,

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